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Date of Filing	:	21 JANUARY 2002 (21/01/2002)
Application number	:	200200342-4
Applicant(s)	:	NANYANG TECHNOLOGICAL UNIVERSITY
Title of Invention	:	ULTRASONIC TREATMENT OF BREAST CANCER

Chig Kam Tack (Mr)
Assistant Registrar
for Registrar of Patents
Singapore

22 January 2003

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(CHAPTER 221)
THE PATENTS RULES

Rule 19

21 JAN 2002

200200342-4

The Registrar of Patents
Registry of Patents

REQUEST FOR THE GRANT OF A PATENT

THE GRANT OF A PATENT IS REQUESTED BY THE UNDERSIGNED ON THE BASIS OF THE PRESENT APPLICATION.

I Title of Invention	Ultrasonic Treatment Of Breast Cancer				
II Applicant(s) *(See note 2)*	(a) Name	Nanyang Technological University			
	Body Description/ Residency	A body corporate incorporated in the Republic of Singapore			
	Street Name & Number	c/o Innovations and Technology Transfer Office Blk 1, Unit 213, 16 Nanyang Drive Singapore 637722			
	City				
	State				
	Country	Republic of Singapore			
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	Body Description/ Residency				
	Street Name & Number				
	City				
	State				
	Country				
	(c) Name				
	Body Description/ Residency				
	Street Name & Number				
	City				
	State				
	Country				
III Declaration of priority *(See note 3)*	Country/Country Designated		File No		
	Filing Date				
	Country/Country Designated		File No		
	Filing Date				
	Country/Country Designated		File No		
	Filing Date				

SECOND SCHEDULE – continued

(a) The applicant(s) is/are the sole/joint inventor(s) (b) A statement on Patents Form 8 is/will be furnished	[ ] Yes [ ] No [ ] Yes [ ] No
V **Name of Agent (if any)** *(See note 5)*	Ella Cheong Mirandah & Sprusons Pte Ltd
VI **Address for Service** *(See note 6)*	Block/Hse No: Level No: Unit No/PO Box: 1531 Postal Code: 903031 Street Name: Building Name: Robinson Road Post Office
VII **Claiming an earlier filing date under section 20(3), 26(6) or 47(4)** *(See note 7)*	Application No: Filing Date:
	[Please tick in the relevant space provided]: ( ) Proceeding under rule 27(1)(*a*). Date on which the earlier application was amended = or ( ) Proceeding under rule 27(1)(b).
VIII **Invention has been displayed at an International Exhibition** *(See note 8)*	[ ] Yes [X] No
IX **Section 114 requirements** *(See note 9)*	The invention relates to and/or used a micro-organism deposited for the purposes of disclosure in accordance with section 114 with a depository authority under the Budapest Treaty. [ ] Yes [X] No
X. **Check List** *(To be filled in by applicant or agent)*	A. **The application contains the following number of sheet(s):-**

1	Request	3	sheets
2	Description	12	sheets
3	Claim(s)	4	sheets
4	Drawing(s)	9	sheets
5	Abstract	1	sheets

B. **The application as filed is accompanied by:-**

1	Priority document	
2	Translation of priority document	
3	Statement of Inventorship & right to grant	
4	International Exhibition Certificate	

XI. **Signature(s)** *(See note 10)*

Applicant (a)	[illegible]
Date	21 January 2002
Applicant (b)	
Date	
Applicant (c)	
Date	

NOTES:

1. This form when completed, should be brought or sent to the Registry of Patents together with the prescribed fee and 3 copies of the description of the invention, and of any drawings.

2. Enter the name and address of each applicant in the spaces provided at paragraph II. Names of individuals should be indicated in full and the surname or family name should be underlined. The names of all partners in a firm must be given in full. The place of residence of each individual should also be furnished in the space provided. Bodies corporate should be designated by their corporate name and country of incorporation and, where appropriate, the state of incorporation within that country should be entered where provided. Where more than three applicants are to be named, the names and address of the fourth and any further applicants should be given on a separate sheet attached to this Form together with the signature of each of these further applicants.

3. The declaration of priority at paragraph III should state the date of the previous filing, the country in which it was made, and indicate the file number, if available. Where the application relied upon in an International Application or a regional patent application e.g. European patent application, one of the countries designated in that application [being one falling under the Patents (Convention Countries) Order] should be identified and the name of that country should be entered in the space provided.

4. Where the applicant or applicants is/are the sole inventor or the joint inventors, paragraph IV should be completed by marking the "YES" Box in the declaration (a) and the "NO" Box in the alternative statement (b). Where this is not the case, the "NO" Box in declaration (a) should be marked and a statement will be required to be filed on Patents Form 8.

5. If the applicant has appointed an agent to act on his behalf, the agent's name should be indicated in the spaces available at paragraph V.

6. An address for service in Singapore to which all documents may be sent must be stated at paragraph VI. It is recommended that a telephone number be provided if an agent is not appointed.

7. When an application is made by virtue of section 20(3), 26(6) or 47(4), the appropriate section should be identified at paragraph VII and the number of the earlier application or any patent granted thereon identified. Applicants proceeding under section 26(6) should identify which provision in rule 27 they are proceeding under. If the applicants are proceeding under rule 27(1)(a), they should also indicate the date on which the earlier application was amended.

8. Where the applicant wishes an earlier disclosure of the invention by him at an International Exhibition to be disregarded in accordance with section 14(4)(c), then the "YES" Box at paragraph VIII should be marked. Otherwise the "NO" Box should be marked.

9. Where in disclosing the invention the application refers to one or more micro-organisms deposited with a depositary authority under the Budapest Treaty, then the "YES" Box at paragraph IX should be marked. Otherwise the "NO" Box should be marked.

10. Attention is drawn to rules 90 and 105 of the Patent Rules. Where there are more than three applicants, see also Note 2 above.

11. Applicants resident in Singapore are reminded that if the Registry of Patents considers that an application contains information the publication of which might be prejudicial to the defence of Singapore or the safety of the public, it may prohibit or restrict its publication or communication. Any person resident in Singapore and wishing to apply for patent protection in other countries must first obtain permission from the Singapore Registry of Patents unless they have already applied for a patent for the same invention in Singapore. In the latter case, no application should be made overseas until at least two months after the application has been filed in Singapore.

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ULTRASONIC TREATMENT OF CANCERS

Field of the Invention

This invention relates to the treatment of cancers. It relates particularly to the use of focused ultrasonic energy to treat cancers/tumours in the breast, and in the organs through the clear acoustic window of the abdominal and supra-pubic routes.

Background of the Invention

Cancer is a life-threatening medical condition that is deserving of serious scientific and medical investigation with a view to finding improved curative treatments. Breast cancer is the most frequent form that occurs in women. Other common susceptible sites in the abdomen – affecting both men and women - are the kidney, liver, colon and stomach.

Two broad categories of cancer treatment are: direct surgical manipulation on the affected tissue and non-invasive treatment. Non-invasive techniques utilise modalities such as X-rays, lasers, microwave, hyperthermia, cryoablation etc., the selection of which depends upon the stage, size, shape and position of the target area. Ultrasound is known to be useful as one form of hyperthermia. Single focused transducers, however, are not very flexible in creating a desired spatial distribution of ultrasound energy within the treatment field. This is because they have a fixed focal depth and frequency of operation. Also, the size of the focal region may not match the size of the tumour. To treat the whole abnormal region, an ultrasonic beam needs to be mechanically scanned over the target area. Besides this, the residual amount of energy residing in dispersion zone and its overlap during scanning over the target region may result in undesirable hot-spots in the overlying normal tissue.

High Intensity Focused Ultrasound is a non-invasive technique capable of selective destruction of tissue volumes within the body. The aim is to produce damage in

the focal region of an acoustic beam in a predictable and reproducible manner, while sparing overlying and surrounding tissue. A specific multi-probe technique, such that the individual probes are excited in unison, at comparatively low power levels, is known.

One example of this known approach – for use in the treatment of brain cancers – is described in the publication: Chauhan, S, Davies, B.L., Lowe, M.J., ' A Multiple Focused Probe System for HIFU-based Neurosurgery', *Ultrasonics*, vol 39, 33-44, 2001. This approach, as outlined in the publication, is not directly applicable to the treatment of abdominal and breast cancers. There are important anatomical differences between the human torso and head, most notably the bone enveloping the brain. As such, no immediate acoustic window to the brain is available without removing a section of the skull. This limits the ability to manipulate the orientation of the ultrasonic transducers. In the abdomen, it is the ribs that pose obstacles to an acoustic window, however there are interstices between the ribs that make orientation of the ultrasonic probes easier.

It is an object of the present invention to provide a form of focused ultrasonic treatment of cancers that seeks to improve the efficacy of such a modality, and reduce the unwanted damage to normal tissue.

Summary of the Invention

The invention discloses a method for the ultrasonic treatment of a cancer in subject tissue, comprising the steps of:

diagnosing the site of a target tumour by ultrasound;

robotically manipulating an array of two or more ultrasonic treatment probes, that are mechanically focused onto a con-focal region, to sight said focal region on at least a portion of said target tumour; and

activating said probes to ablate said portion of the target tumour.

The invention further discloses apparatus for the ultrasonic treatment of cancer in subject tissue, comprising:

an array of (i) two or more ultrasonic treatment probes, that are mechanically configurable to be focused onto a desired con-focal region, and (ii) an ultrasonic diagnostic probe;

a robotic manipulator, carrying said array, and operable to move said array and thus sight said focal region; and

a programmed controller which operates to activate said probes and said cause motion of robotic manipulator in a manner such that the diagnostic probe is scanned over at least a portion of the tissue to diagnose the site of a target tumour, and the treatment probes are sighted such that the focal region coincides with at least a portion of the target tumour and are activated to ablate said portion of the target tumour.

The invention yet further discloses a jig array assembly for ultrasonic treatment probes comprising:

a central shaft;

two or more segmented collars, in a stacked manner rotatably of said shaft, and adapted to be fixed in a chosen orientation by fastening means;

a respective mounting member extending from each said collar, and providing mounting point, said mounting point lying in a common plane orthogonal to said shaft;

a respective arm attached at the end to a respective mounting point; and

a respective probe holder attached to the other end of each said arm.

Brief Description of the Drawings

In the drawings:

Figure 1 is a perspective view of a surgical treatment assembly;

Figures 2A, 2B and 3 are perspective views of a probe jig assembly in three configurations;

Figure 4 is a schematic diagram showing the range of controlled movement that may achieved by the robotic manipulator;

Figure 5 is a perspective view of the robotic manipulator assembly;

Figure 6 is a schematic block diagram showing the control circuitry and interface to the robotic manipulator;

Figure 7 shows the clinical treatment assembly in use;

Figure 8 is a perspective view of a framed cup element of the surgical treatment apparatus;

Figure 9 is a schematic block diagram of the operational modes of the surgical treatment; and

Figure 10 shows a sample display representing surgical planning using a graphical user interface.

Detailed Description

An embodiment will be described with reference to the treatment of breast cancer. In particular, a method of treatment, a clinical treatment assembly, a robotic manipulator and controlling arrangements therefor will be described. It should be understood, however, that the invention is not so limited. The various aspects are equally applicable to the treatment of other forms of cancer through soft tissue acoustic windows. Embodiments of the invention also can be applicable in a purely diagnostic mode.

Mechanical and Electrical Arrangement

Figure 1 shows a surgical treatment assembly 10 in broad detail. An operating table 12 has an operating window 14 that is arranged to receive the patient's breasts. The subject breast is received into a half-hemispherical framed cup 15 to descend into a tank 16 containing a coupling medium (e.g. degassed water). The patient's breasts are isolated from the couplant by an elastic membrane forming a boundary of the operating window 14. Suitable forms of membrane include latex or polyurethane. A robotic manipulator 18 is sited partially underneath and partially within the tank 16, and carries the ultrasonic probe assembly 30 used for the treatment of the subject breast. Operational controls are housed within a cabinet 20, mounted on the base of the operating table 12. The relative

location of the frame 15 and the robotic manipulator 18 is such that the subject breast will be within the range of motion of the robotic manipulator.

Turning then to Figure 2A, a first form of jig assembly 30 is shown. A central shaft 32 has three segmented collars 34, 36, 38 arranged in a stacked manner on the shaft. Each collar can rotate about, and be fixed into position on the shaft, typically by a grub screw or the like (not shown). Each collar has attached to it a mounting member 35, 37, 39. The top and bottom mounting members 35, 39 in the stack provide an offset such that all three members provide a mounting point that is co-located in the horizontal plane through the central collar 36 (i.e. having a common origin). Extending from the mounting point of each mounting member 35, 37, 39 is an arm 40, 42, 44, at the free end of which is a sleeve 46, 48, 50, into which is received respective ultrasound transducer probes. These probes 52, 54, 56 are best seen in Figure 2B.

The orientation of the probes can be adjusted to give a desired con-focal region by the relative positioning of the arms 40, 42, 44 with respect to the shaft 32 (i.e. the inter-probe angle), and the respective lengths of the arms 40, 42, 44. These relative lengths determine the angles of the sleeve 46, 48, 50 (and thus the respective probes 52, 54, 56) from the horizontal plane. The embodiment of Figure 2A differs from that of Figure 2B in this regard.

For the configuration of Figures 2A and 2B, a symmetrical focal region is achieved. For the example of Figure 3, in which only two probes are in use, a focal region of an irregular (thin) shape is achieved. The range of adjustments described allows a focus region to be identified within a half-hemispherical volume of space; this broadly representing the volume occupied by a breast.

The resultant shape of focal region can be manipulated further by the choice of probe, such that small clusters of cancer cells can be sighted. It is envisaged that the minimum number of treatment probes is two, since a degree of superimposition must be achieved in the focus region. Equally, more than three probes may be utilised – the

decision is a clinical one based upon the location and localised shape of the subject tumour itself. In other words, a desired spatial focal region is designed by way of the number, type and relative orientation of the probes.

The treatment probes typically are extra-corporeal, spherical bowl types, operating in unison at 2 MHz and a focal depth of 65 - 80 mm. The focal region of an individual probe is oblate in shape with typical dimensions of 18 mm and 1.5 mm. In the multiple probe approach, the desired flexibility can be achieved in the shape, size and energy distribution within the con-focal region by orienting the probes in a specific configuration.

The ultrasonic radiation from the respective probes 52, 54, 56 superimposes in a con-focal manner so that there is, in combination, a heating effect sufficient to raise the temperature in that focal region to ablate the targeted cancer cells. The surrounding tissue, through which the respective ultrasonic waves pass, is spared.

Of course, once the probes are fixed into alignment it is only movement of the shaft 32 that can 'move' the focal region in space. In other words, a cancer in the breast typically is of a far greater size then the focal region, and thus a path needs to be traversed by the focal region in order to ablate the entire tumour site. This function is achieved by the robotic manipulator 18.

The shaft 32 is adapted to receive at its free end a further ultrasonic diagnostic probe 58. The purpose of this probe 58 is to provide an image of the target tissue as a function of distance, that can be used to define positioning of the focus region achieved by the treatment probes, as will be explained in further detail below.

Referring then to Figures 4 and 5, these show, respectively, a generalised schematic diagram and a detailed mechanical arrangement drawing of the location of the robotic manipulator 18 and the jig assembly 30 within the tank 16. The shaft 32 supporting the three probes 52, 54, 56 mounts from a carriage 60 that is able to be moved,

in a controllable manner, in the horizontal plane carried on a platform 62, by an electrical motor 63. The platform 62 is mounted on a further shaft 64 that passes through a water-tight joint 66 in the base of the tank 16, terminating on a rotary stage 68. The stage causes the shaft 64 to be rotated by a further electrical motor 69. The rotary stage 68 is carried by a further carriage 70 that mounts from a vertical platform member 72. A yet further electrical motor 74 causes the carriage 70 to be controllably moveable in the vertical plane. The x and y motion can be achieved by a screw thread or belt-driven arrangement. Other arrangements, apparent to one skilled in the art, also are possible. In this way a 3-axis (x, y, θ) robotic manipulator is achieved.

Plainly, the elements of the robotic manipulator within the tank need to be appropriately protected from water ingress.

Figure 6 shows an electrical schematic diagram representing control and signaling for the robotic manipulator, and the treatment and diagnostic probes. A PC-based computer 80 is programmed to control the operation of the robotic manipulator and the probes in a manner that will be described below. It has an output control signal bus (of any inconvenient form) which provides control signals to three servo-controllers, respective being for the 3-axis movement of the robotic manipulator. The x-servo unit 84 drives the x-axis motor 86. The z-servo unit 88 drives the z-axis motor 90. The θ-servo unit 92 drives the θ-axis motor 94.

The control signals also control the respective amplifier units 96, 98, 100 that provide power to excite the respective treatment probes 52, 54, 56. Each of the motors 86, 90, 94 of the robotic manipulator includes a form of optical encoder 102, 104, 106 that provides a relative location (i.e. distance) feedback signal on the input data bus 108.

A diagnostic drive unit 110 provides excitation to the diagnostic probe 58. The probe 58 returns an ultrasound image of a scanned field as a function of distance. This image signal is provided to the input data bus 108.

Diagnostics and Treatment

Figure 7 shows the surgical assembly 10 in use. A subject lies face down (i.e. prone) on the operating table 12. The subject breast is received in the framed cup 15 to descend through the operating window 14 being supported by an elastic membrane 114. The framed cup 15 is shown in detail in Figure 8, having a rim 117, and three arcuate arms 118 ending in a ring 119. The tank 16 is filled with degassed water 116, providing a medium/couplant for effective transfer of ultrasound energy into the breast. The jig assembly 30 has been mechanically pre-configured and is under control of the robotic manipulator 18. Diagnostics and/or treatment is then undertaken.

Diagnostic Mode

The diagnostic mode is used to identify the location of, and shape of cancerous tissue in the breast. This is achieved by use of the diagnostic probe 58 which is arranged to propagate an ultrasonic wave to a known depth into the breast and then progress in the z-axis to perform a slice-wise scan of the breast. The breast is mapped to a coordinate system operating in three dimensions (typically a Cartesian system). Such a diagnostic procedure can be useful to diagnose tumours in the breast, without subsequent implementation of the ultrasonic treatment, since it may be the cell cluster is a benign lump or cyst, or chosen to implement an alternative modality of treatment.

Planning and Treatment Mode

Referring now to Figure 9, a block flow diagram shows the logic flow of pre-surgical planning and on-line surgical planning. Central to the pre-surgical and on-line surgical planning is the provision of a graphical user interface 120. In other words, the pre-surgical and on-line procedures are undertaken by the physician solely by use of the GUI 120.

The pre-surgical planning constitutes the initialisation of HIFU parameters that effect the thermal dose (step 122). These parameters include the electrical power levels to individual probes (calculated from the acoustical intensity required for ablation in a particular tissue/organ type, taking in to account the transducer probes' specifications), exposure time, probe orientation, and couplant temperature. The exposure parameters depend on the shape, size and extent of the cancer/tumour, as deduced by the radiologist/oncologist during pre-surgical analysis/diagnosis, and define the thermal dose. Indeed, the characteristic of the tumour can be determined from a diagnostic mode of operation of the apparatus (discussed above) or by other, conventional imaging modalities. The joint power levels typically are in the ranges: 100-150 W (electrical), which manifests itself into an acoustic intensity in the exposures (i.e. *lesions)* formed that are required to ablate the target tissue. The typical exposure levels are 2-8 sec with a subsequent cooling of 10-15 sec at a given exposure site.

In the on-line surgical planning, the subject, in an anaesthetised state, is firstly accomodated, as discussed with reference to Figure 7, then an initial robot homing operation is performed (step 124) whereby the robotic manipulator defines its coordinates system (step 126). The diagnostic probe 58 has a role here in proximity sensing or localisation with reference to the site.

It is now necessary to accurately relocate the tumour, i.e. notwithstanding that this has been performed in the pre-surgical planning stage (step 128). This is achieved through use of the diagnostic probe 58, that is robotically manipulated to image a series of two-dimensional slice (typically saggital) through the breast. The physician is able now to confirm the pre-surgical planning (or make adjustments to the relevant parameters), but otherwise has confidence that the robotic manipulator has spatial accuracy with respect to the actual location of the subject tumour.

The physician now has a pseudo three-dimensional image of the breast from which the location of a tumour can be accurately determined. The physician now demarcates the affected area of the breast (step 130). References is made here to Figure

10, which is a single frame (i.e. single slice) of the graphical user interface 120 showing the process of demarcation.

The physician has the choice of siting a single lesion, siting as series of lesions in a single plane, or siting lesions for the whole volume of the tumour before applying the focused ultrasonic treatment. One of the considerations in making this choice is that the shape of the tumour may change after treating any individual lesion.

Once the set of lesions has been so identified, then the surgical procedure may commence by application of treatment energy to the configured treatment probes, 52, 54, 56 (step 132). Such treatment can be in an automatic or manual mode. In other words, the robotic manipulator can be controlled by the physician to 'fire' and then site the next lesion, or the robotic manipulator can execute all lesions in a programmed manner. The treatment ends when the last frame is reached (step 134).

For the present apparatus, the concept of safety is grossly different from industrial robots, that aren't designed/configured to work in vicinity of human beings. Surgical/medical robots are required to function near and 'inside' humans, with human co-operation and intervention, thus safety principles cannot be adopted directly from fully autonomous and versatile industrial machines. Due to the precarious nature of human anatomy and physiology, and thus the suitably selected medical for a particular treatment, a surgical/medical robot must be the subject of a stringent safety regimen.

Mechanically, the robotic system is configured to move in a restricted and well-defined work-envelope. The practical work-envelope of the manipulator encompasses the human torso, and thus is capable to reach and treat cancers/tumours through soft tissue windows in this region (such as breast tissue, trans-abdominal, supra-pubic and rib interstices). However, for a specific intervention in a specific tissue (i.e. in a breast, as described above) and after patient registration and homing stage, the robot is configured to move the jig assembly 30 only in a subset of the available work-envelope with suitably demarcated 'go' and 'no-go' areas. Safety limit switches and mechanical interlocks may

be provided to restrict the motion in that area only. The primary control, however, is to restrict the trajectory by software. For instance, in the case of breast tissue, an annular cylindrical area is allowed as 'go' area. The radius of the 'no-go' inner cylinder is same as the framed cup 15, followed by a 'go' outer annular ring area with extended radius equivalent to the focal depth of selected ultrasonic probes, followed by a 'no-go' area in rest of the tank. This is done to ensure the probes enveloping the decended breast can not hit the organ/tissue at any stage of intervention during the lesioning process.

Another safety feature can be incorporated in the energy deployment to the probes. The treatment typically comprises an exposure of 2-8 secs, followed by cooling/dead time. The power supply to the robot is accordingly programmed such that the energy sub-system to the probes is dormant during any 'robot move' operation. Once the robot places the jig assembly 30 at a suitable lesioning position, the power to the robot is 'cut-off'. In this way, the robot can not more during the application of ultrasonic energy.

The embodiment described is with reference to treatment of breast cancer, however, as foreshadowed, treatment of other cancers through abdominal or trans-pubic routes are contemplated. The surgical assembly would need to be modified to provide the appropriate acoustic window onto the body and the jig assembly also may need to be reconfigured to better suit the gross physical anatomy of the treatment site.

Embodiments of the invention offers specific advantages in that there is precise control over the ultrasonic energy to effectively ablate the site of tumours. Precise lesions may be obtained to give effective destruction of only the tumour cells. A reducion in the duration of intervention, and precise control in terms of crude and fine adjustments is made possible. The ability to treat the entire volume of a tumour under automatic robotic control removes the requirement of the physician/radiologist to have the extensive experience of visualising the three-dimensional region and manually guide a probe to the next suitable location/plane. Traditional surgery on a 2 cm tumour may take up to 2 hours to perform. In contrast, treatment by the present apparatus may take a

greatly reduced time, even of the order of only 20 minutes. For example, the physician can chose to program and place any two subsequent lesions far away from each other in the affected region and thus optimising a lower or absent 'cooling zone' after each exposure. The reduced time under anaesthetic is beneficial to the subject.

Numerous alterations and modifications, as would be apparent to one skilled in the art, can be made without departing from the broad inventive concept.

Claims:

1. A method for the ultrasonic treatment of a cancer in subject tissue, comprising the steps of :

diagnosing the site of a target tumour by ultrasound;

robotically manipulating an array of two or more ultrasonic treatment probes, that are mechanically focused onto a con-focal region, to sight said focal region on at least a portion of said target tumour; and

activating said probes to ablate said portion of the target tumour.

2. A method as claimed in claim 1, comprising the further step of manipulating the array to sight on one or more other focal regions of said target tumour.

3. A method or claimed in claim 2, wherein said manipulations are performed as a series of step-wise motions in one plane.

4. A method as claimed in any one of the preceding claims, wherein the step of diagnosing the site of a target tumour includes:

ultrasonically scanning at least a portion of subject tissue in a series of step-wise slices to derive a pseudo three-dimensional representation thereof.

5. A method as claimed in any one of the preceding claims, comprising the further step, following the diagnosis step, of mechanically configuring said array of probes to give a desired convergent con-focal region.

6. A method as claimed in claim 5, wherein said activating step is performed with predetermined probe parameters, determining thermal dose.

7. A method as claimed in claim 6, wherein said parameters include one or more of frequency, power and on-time.

8. A method as claimed in any one of the preceding claims, comprising the further initial steps of defining a safe working envelope for said robotic manipulation step.

9. A method as claimed in claim 8, wherein said robotic manipulation is interlocked with said activation such that both steps can not occur simultaneously.

10. A method as claimed in any one of the previous claims comprising the further, initial step of locating a patient in an orientation such that said target tumour site is within the range of motion of said array.

11. A method as claimed in claim 10, restricted to treatment of cancers in the breast.

12. Apparatus for the ultrasonic treatment of cancer in subject tissue, comprising:

an array of (i) two or more ultrasonic treatment probes, that are mechanically configurable to be focused onto a desired con-focal region, and (ii) an ultrasonic diagnostic probe;

a robotic manipulator, carrying said array, and operable to move said array and thus sight said focal region; and

a programmed controller which operates to activate said probes and said cause motion of robotic manipulator in a manner such that the diagnostic probe is scanned over at least a portion of the tissue to diagnose the site of a target tumour, and the treatment probes are sighted such that the focal region coincides with at least a portion of the target tumour and are activated to ablate said portion of the target tumour.

13. The apparatus of claim 12, wherein said controller activates said robotic manipulator to sight and operate the treatment probes at other focal regions coinciding with the target tumour.

14. Apparatus as claimed in claim 13, wherein said controller activates said robotic manipulator as a series of step-wise motions in one plane to sight and operate the treatment probes in aggregation to coincide with the target tumour in that plane.

15. Apparatus as claimed in any one of claims 12 to 14, wherein said robotic manipulator operates to cause the diagnostic probe to scan at least a portion of the subject tissue as a series of step-wise slices to derive a pseudo three-dimensional representation thereof.

16. Apparatus as claimed in any one of claims 12 to 15, wherein said array of probes is mechanically configured to give a desired focal region matching to the site of the diagnosed tumour.

17. Apparatus as claimed in claim 16, wherein said ultrasonic treatment probes have predetermined parameters determining thermal dose.

18. Apparatus as claimed in any one of claims 12 to 17, further comprising a procedure table upon which a subject can lie, having an acoustic window therein at which said subject tissue is sited.

19. Apparatus as claimed in claim 18, wherein the acoustic window is arranged to be aligned with the breast of a subject.

20. Apparatus as claimed in any one of the claims 9 to 19, wherein said controller in programmed to define a safe working envelope for the array.

21. Apparatus as claimed in claim 20, wherein said controller further interlocks said treatment probes and said robotic manipulator so that neither can be operated simultaneously.

22. A jig array assembly for ultrasonic treatment probes comprising:

a central shaft;

two or more segmented collars, in a stacked manner rotatably of said shaft, and adapted to be fixed in a chosen orientation by fastening means;

a respective mounting member extending from each said collar, and providing mounting point, said mounting point lying in a common plane orthogonal to said shaft;

a respective arm attached at the end to a respective mounting point; and

a respective probe holder attached to the other end of each said arm.

23. An assembly as claimed in claim 22, wherein said arm are of chosen lengths.

24. An assembly as claimed in either one of claim 22 or claim 23, further comprise a diagnostic ultasonic probe mounting point located at an end of the shaft.

Abstract

Ultrasonic Treatment of Cancers

A method of treatment, clinical treatment assembly, robotic manipulator and controlling arrangements for the treatment of cancers are described. The invention has particular application in the treatment of breast cancer. A robotic manipulator (18) carries a jig assembly (30). The jig assembly (30) includes an array of treatment probes (52, 54, 56) and a single diagnostic probe (58). The probes can to be moved by the robotic manipulator (18) in three directions (x, y, θ). A subject breast tissue is received in a tank (16) through an operating window (14), and the robotic manipulator (18) is to firstly diagnose the sight of a tumour in the breast tissue. Once the tumour has been located by use of the diagnostic probe (58), the treatment probes (52, 54, 56) are used to ablate the tumour by the superposition of ultrasonic waves at a focal region. A series of such lesions may be performed in sequence to traverse the full extent of the tumour.

(Fig. 2)

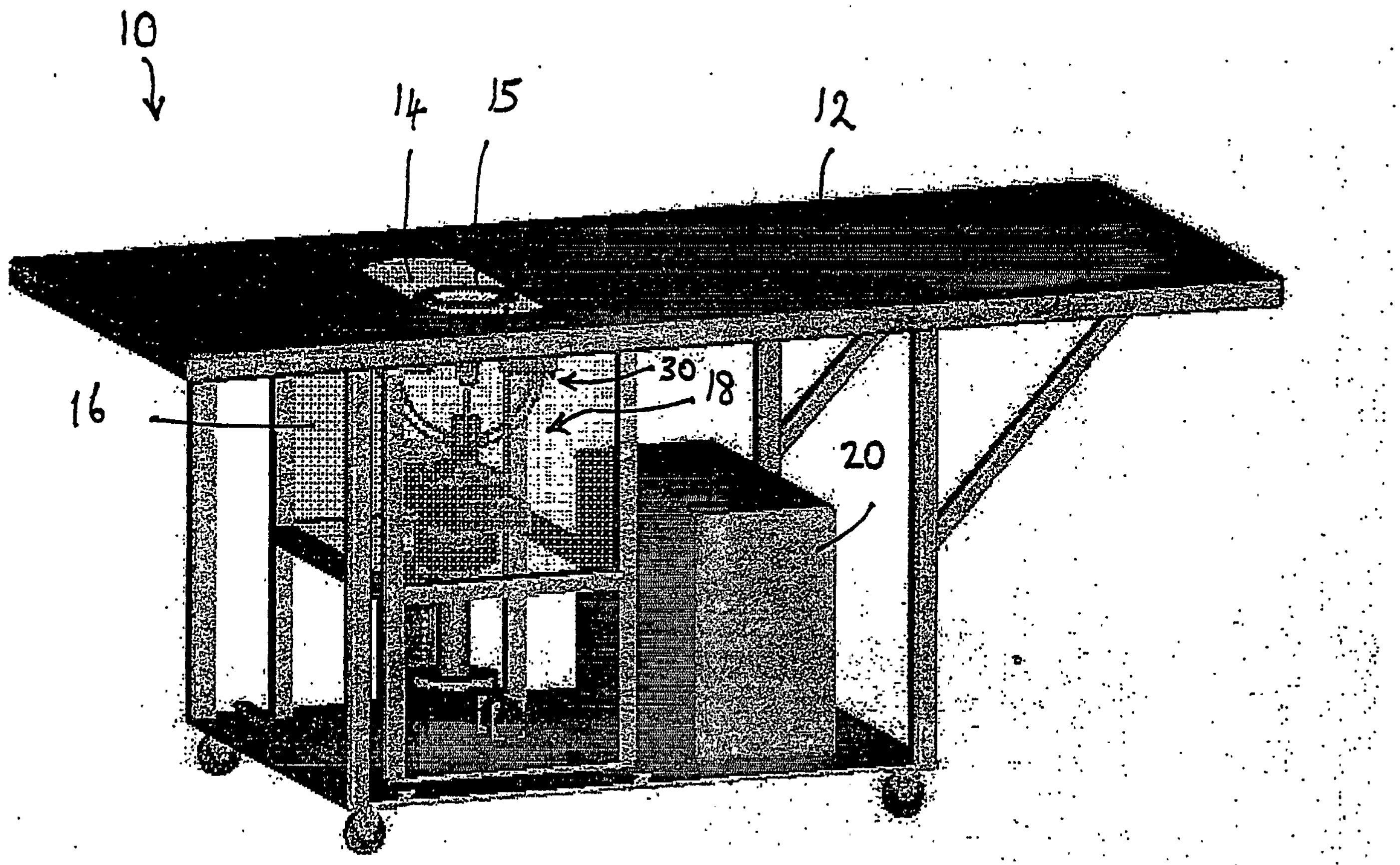


Fig. 1

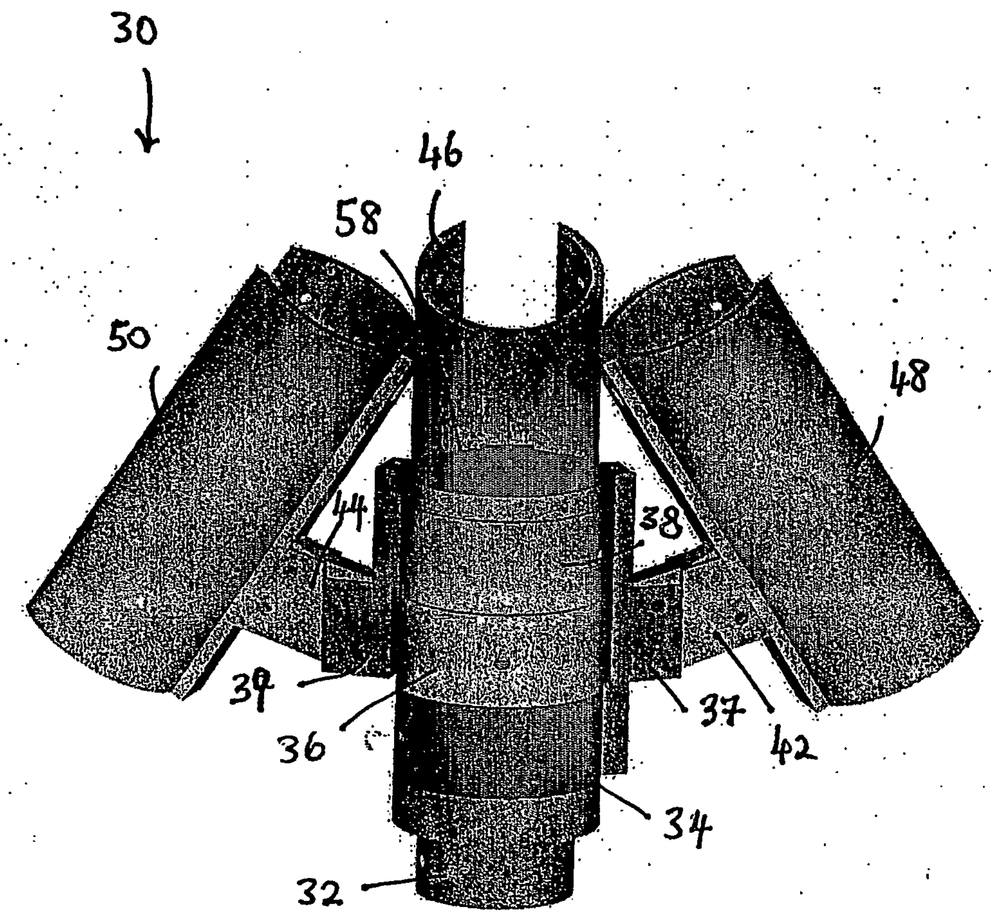
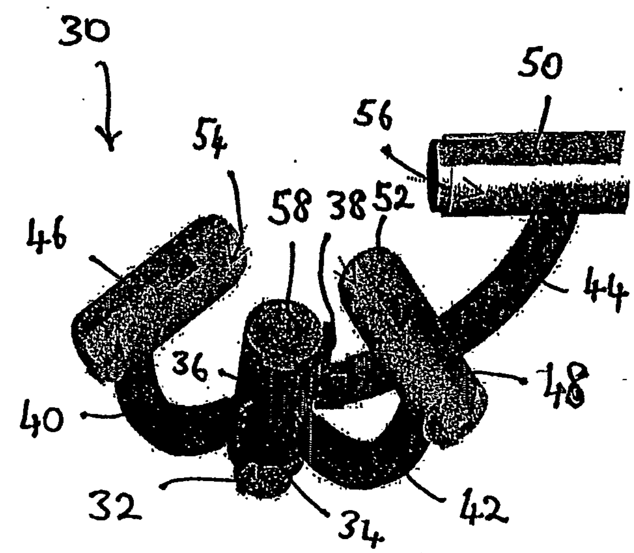


Fig. 2A


30
50
56
54
58
38
52
46
44
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48
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32
34
42

Fig. 2B

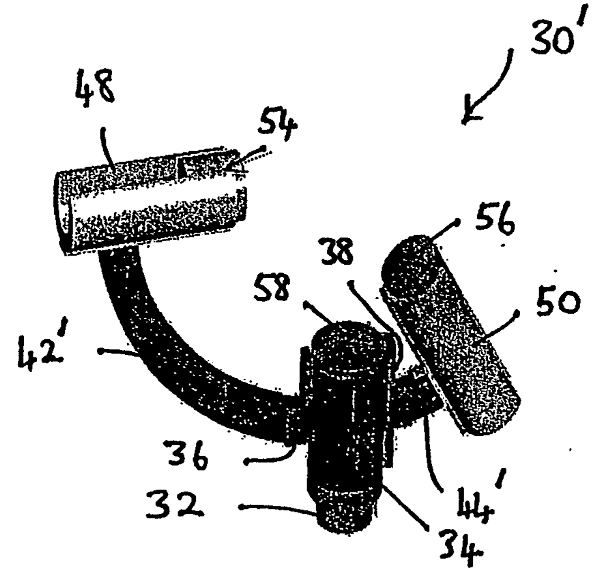

30'
48
54
56
38
58
50
42'
36
44'
32
34

Fig. 3

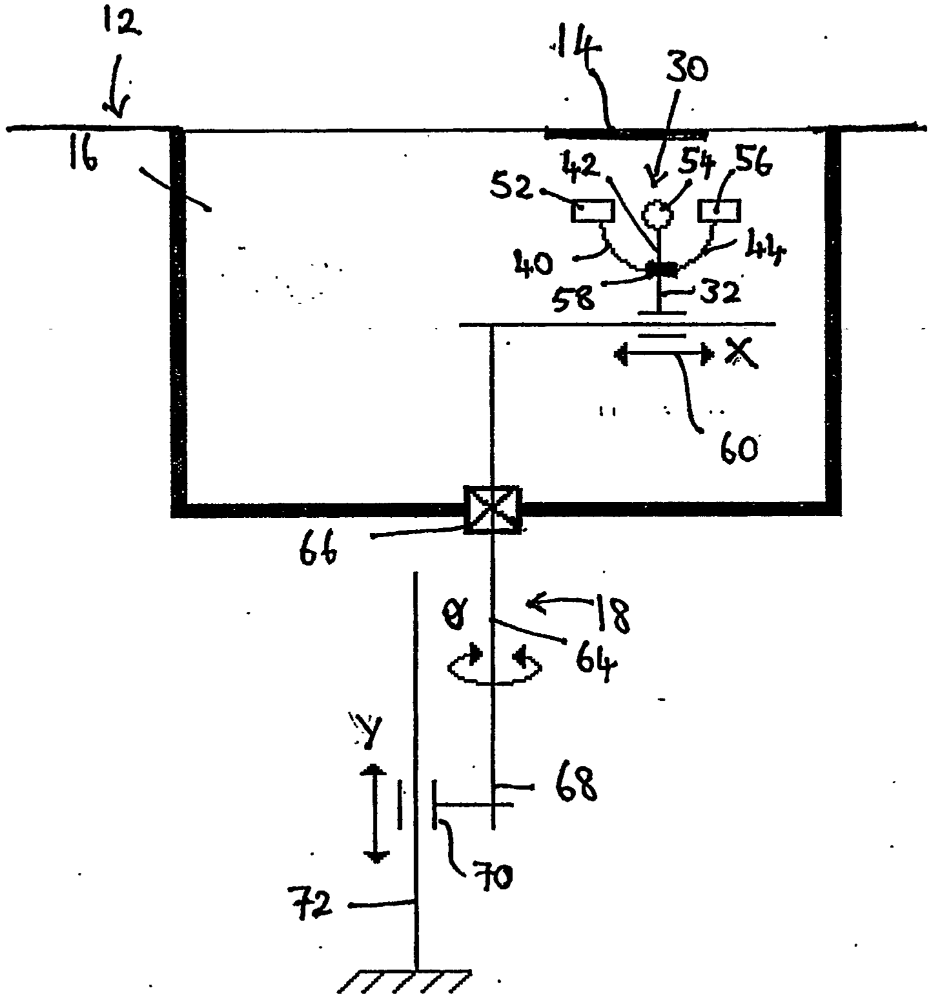


Fig. 4

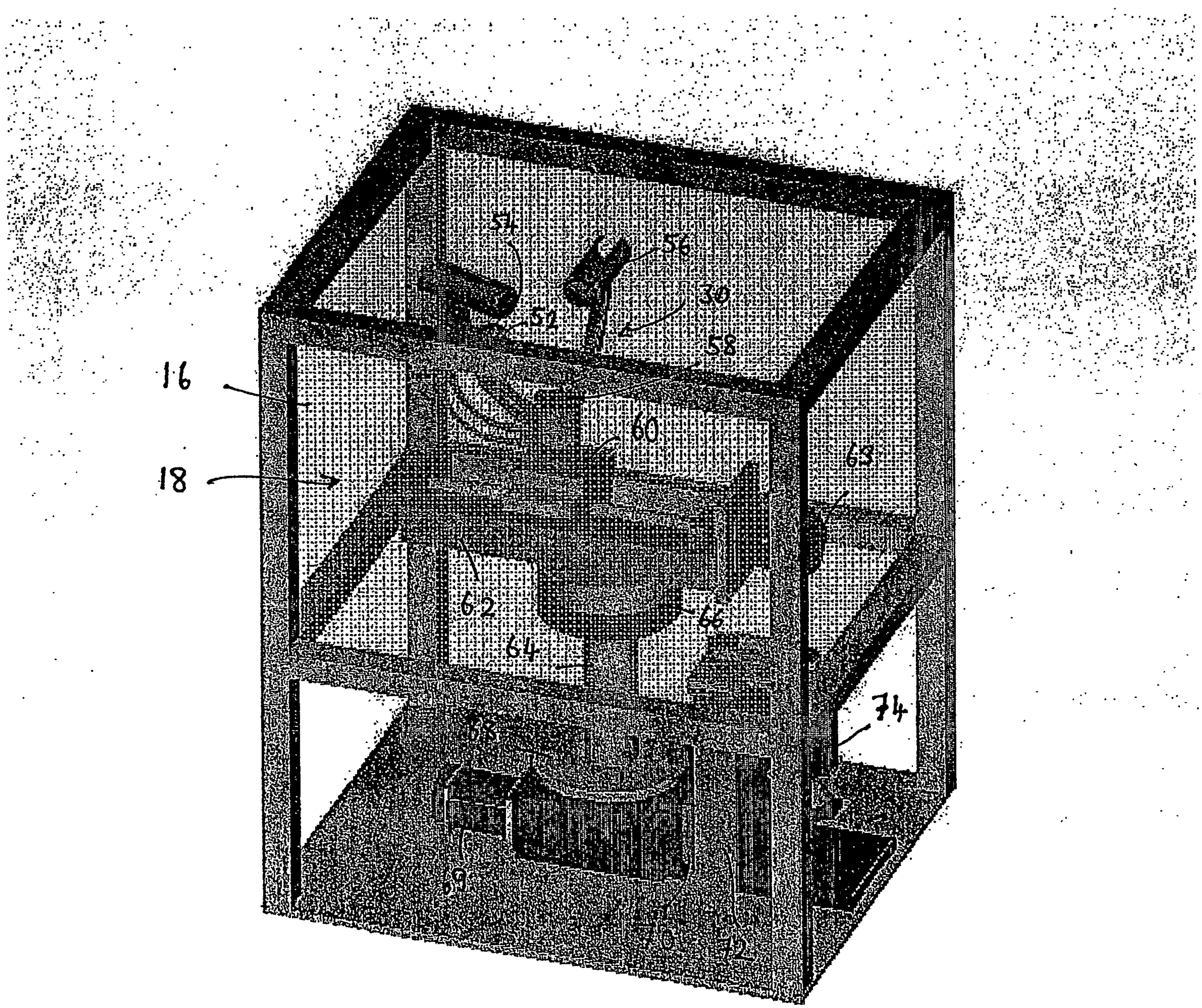
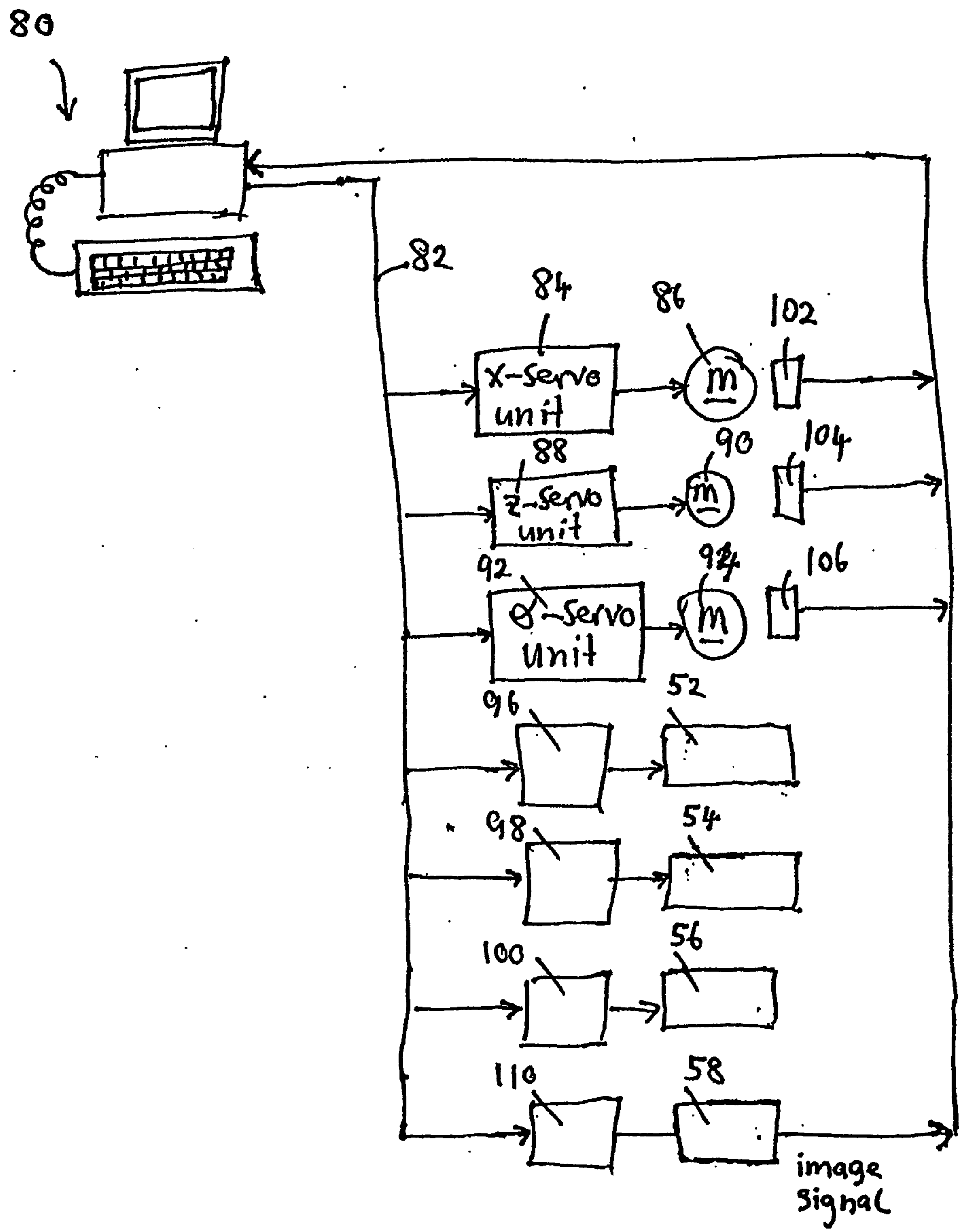


Fig-5



80
82
84
86
102
X-servo unit
m
88
90
104
z-servo unit
m
92
94
106
θ-servo unit
m
96
52
98
54
100
56
110
58
image signal

Fig. 6

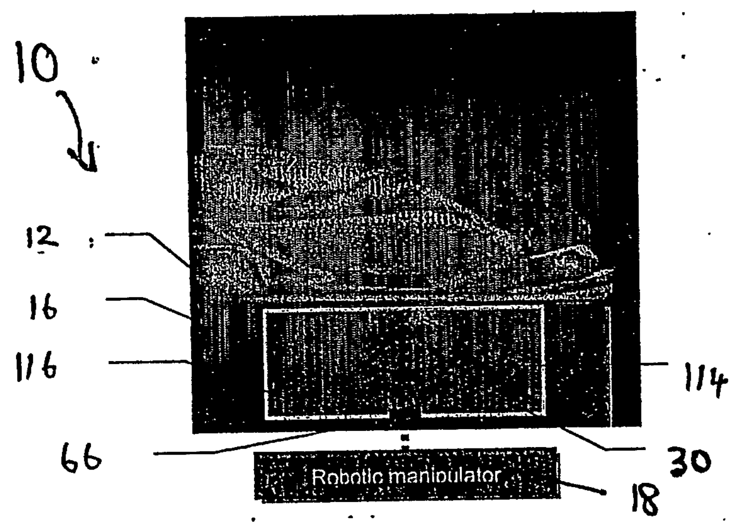

10
12
16
116
114
66
30
Robotic manipulator
18

Fig. 7

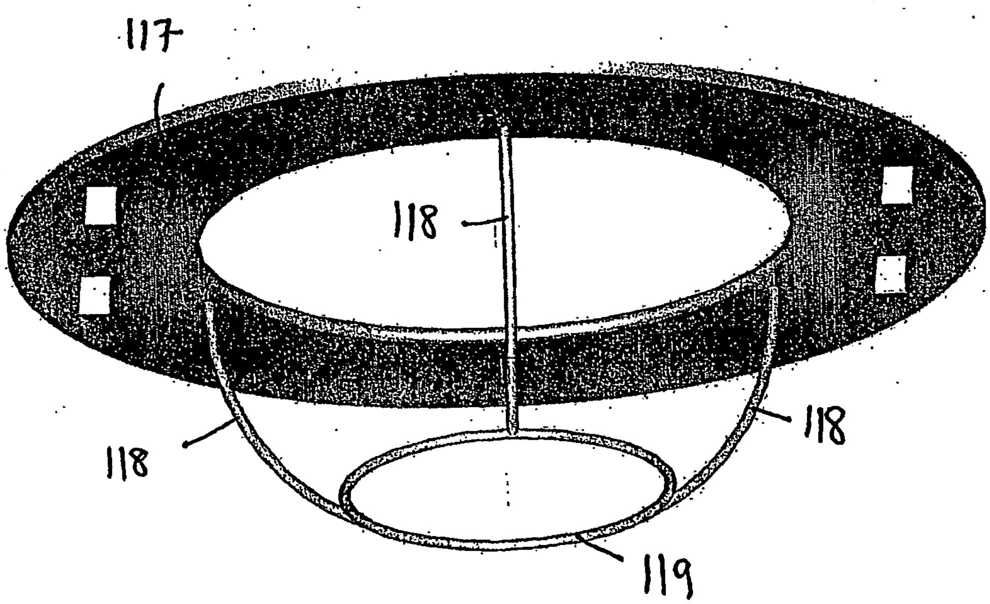
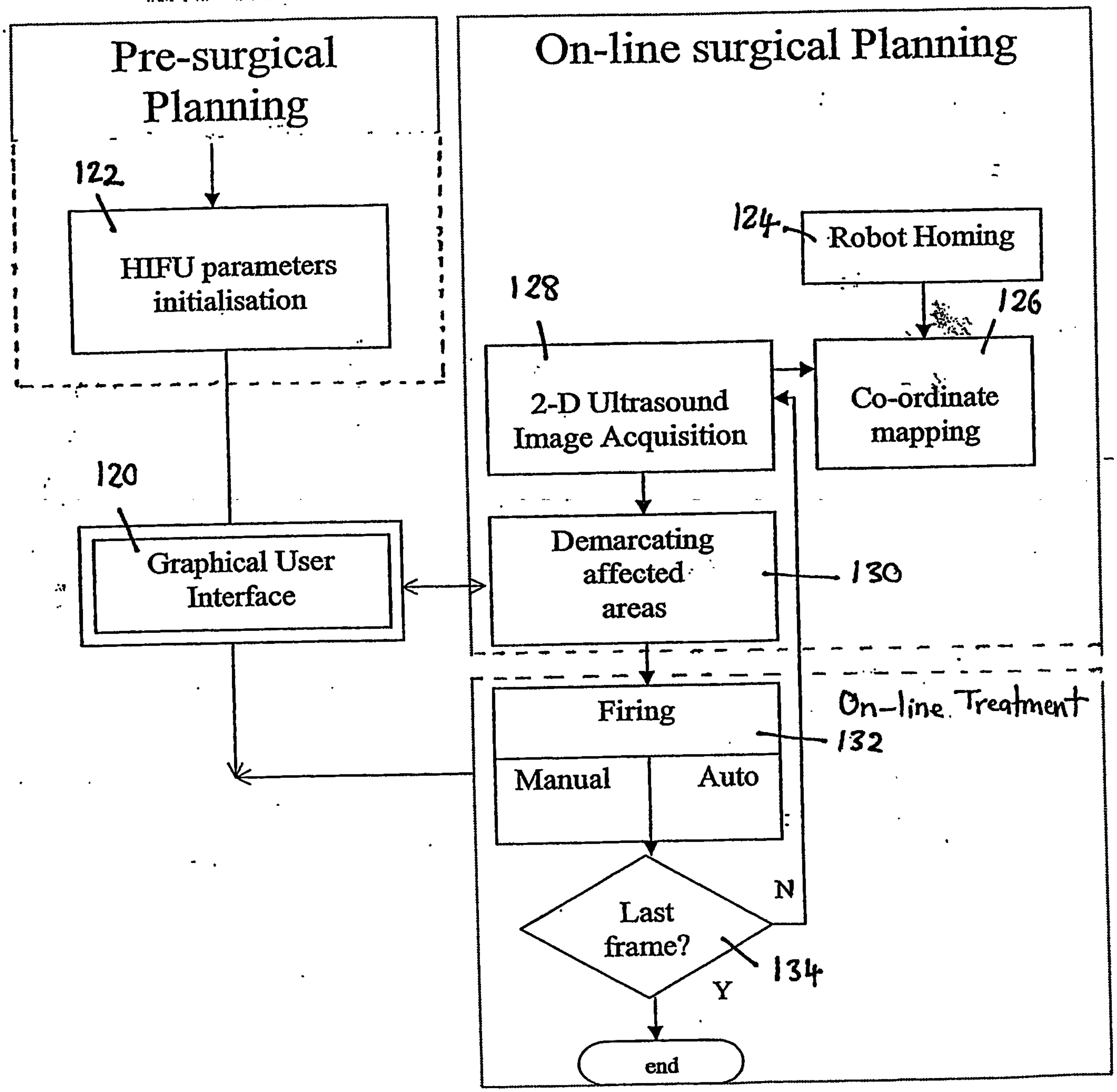

117
118
118
118
119

Fig. 8



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Last frame?
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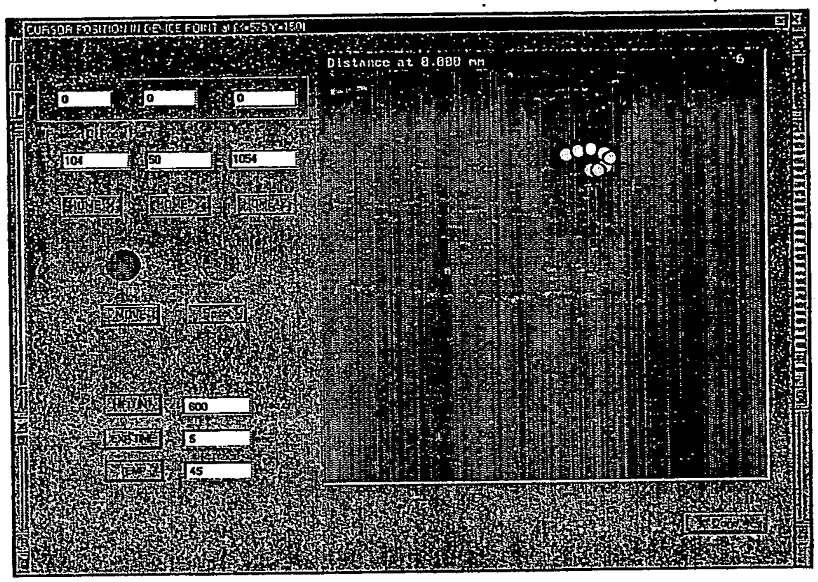

Fig. 10